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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,431	12/03/2003	Knut Brabrand	09032.0001	5321

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

JAWORSKI, FRANCIS J

ART UNIT

PAPER NUMBER

3768

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/725,431	BRABRAND, KNUT	
	Examiner	Art Unit	
	Jaworski Francis J.	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,7,9-14 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-7,9-14,17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6-7, 14 and 20-21 are rejected under 35 USC 103(a) as obvious based on Prince (US6937883 as argued previously, further in view of Iizuka et al (US5355887) where Prince teaches a method and structure for non-invasive determination of a patient's diaphragm position using a one-dimensional phased array longitudinally placed over the liver and adjacent diaphragm to detect diaphragm position, the sinus being adjacent to the diaphragm and therefore being overlaid during its motion, the position of the diaphragm being determined from the beamformed aiming of the array's elements with Doppler processing for tracking of diaphragm motion during locating setup, see col. 10 lines 50 – 67. Iizuka et al merely evidences that an scan by a line array such as placed to cross the diaphragm in ensonation will detect the diaphragm by a reflectivity or impedance difference between received signals and so can be used to track displacement for any point along that line.

Claims 2 – 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prince in view of Iizuka et al as applied to claim 1 above, and further in view of Rieder et al. previously, Riederer is directed to a method of determining the degree of lung

inflation by non-invasively determining the position of the diaphragm with the MRI imaging system itself serving as a diaphragm position sensing device by using the MRI imaging display to display a truncated or navigational pulse scan along a line which transects the diaphragm at a location of its dome which is suitable to be reliably representative of the degree of inflation. During a reference point establishment phase the operator selects a 20 sample wide range over which signal edge extraction is practiced to track diaphragm location which is fed back to the patient by a corresponding 20 LED bar display so that the patient can breath-hold at the optimum diaphragm position with the MRI diagnostic mode image then taken after a short stabilizing delay. Riederer also teaches a calibration-breath-holding technique where the patient first assists in determining a diaphragm-stationary reference point for which the MR image is optimal and thereafter the diaphragm position is returned by breathholding to the stationary reference optimum while diagnostic imaging proceeds. It would have been obvious to supplement Prince in view of Iizuka et al's teaching of using detected impedance of tissue to distinguish tracked point motion with this capability since the Doppler tracking of the diaphragm within the range gate with triggering on the wave curve characteristics is an alternative equivalent to the time-variant LED display of the former within the 20 element range limits.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prince in view of Iizuka et al as applied to claims 7 or above, and further in view of Riederer et al and Amazeen et al (US4431007). Whereas the former does not speak directly to impedance change in the Z-direction with respect to diaphragm movement, Amazeen

et al evidences that echoes such as returning from the patient diaphragm in Prince represent density discontinuities due to impedance changes at such interfaces. Further, since Riederer et al performs the navigational referencing using a longitudinal z-gradient field scanline through the diaphragm (see col. 5 end-portion) the Prince col.6 end-portion discussion may be understood to advise to measure z-direction movement as nearly as possible, since Doppler resolution is greatest along the direction of motion which in the case of the diaphragm is longitudinal along the patient axis.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prince in view of Iizuka et al as applied respectively to claims 1, 7 above, and further in view of Wessels et al (US6314312). Whereas the former while directed to MRI diagnosis at an optimal diaphragm position do not discuss biopsy as an associated procedure, it would have been obvious in view of Wessels et al col. 1 lines 12 – 42 and col. 6 lines 22 – 62 to track organ motion in association with biopsy in order that a small lesion such as P within the liver may be accurately targeted using the ultrasound as part of the tracking where ultrasound is used such as in Prince.

Claims 11 – 12, 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prince in view of Iizuka et al as applied to claim 7 above, and further in view of Hernandez-Guerra et al (EP 0 940 158 A1, of record with the 7/19/04 IDS). Whereas the former is silent as to the use of an ultrasound-array-based non-invasive diaphragm position and motion tracking system for radiation therapy, it would have been obvious in view of Hernandez-Guerra et al to utilize such a device for triggering radiotherapy in association with target movement for the reason provided in the latter,

namely that a non-invasive diaphragm tracking subsystem (the SEFE redundant parameter system described in paras [0049] – [0053]) allows for long treatment times not feasible by breath-holding alone, Prince also being not relegated to a breath-holding application.

Claims 1, 12-13 is also rejected under 35 U.S.C. 103(a) as being unpatentable over Hernandez-Guerra et al further in view Prince and Iizuka et al, since the former meets the claimed limitations (in the case of claim 13 since CPU 18 controls the radiotherapy source head positions) save that diaphragm position is not used as the non-invasive respiratory motion parameter however since the document states in para 53 that diaphragm movement is being tracked then the latter merely provide practicalization thereto, albeit without 4-parameter redundancy which the SEFE algorithm provides.

Mostafavi (US6937696) is cited as of interest in showing fluoroscopic tracking of the diaphragm for radiation therapy triggering, see col. 23 lines 1 – 18.

Feinberg et al (International Published Application WO-02/41776, of record) like Prince is directed to whole-image tracking of displacement (inter alia by regional displacement measurement across successive frames) using a longitudinally positioned ultrasound array, see Fig. 10.

Sontag et al (US6298260) like Hernandez-Guerra uses SEFE-based respiratory triggering.

Schweikard et al detects respiratory motion during treatment regimens.

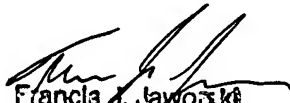
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

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Francis J. Jaworski
Primary Examiner